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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,110	10/16/2003	Matthew F. Brown	PC25202A	7238

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT PAPER NUMBER

1617

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,110

Applicant(s)

BROWN ET AL.

Examiner

Renee Claytor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application claims priority to Provisional Application 60/422573 filed on 10/30/2002. Applicant's priority is acknowledged.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 (in part) 2-22, drawn to a method of treating or preventing fibrosis by administering a pharmaceutically effective amount of a piperazine compound of formula (I), classified in class 514, subclass 255.01.
- II. Claims 1 (in part) 2-22, drawn to a method of treating or preventing Alzheimer's disease by administering a pharmaceutically effective amount of a piperazine compound of formula (I), classified in class 514, subclass 255.01.
- III. Claims 1 (in part) 2-22, drawn to a method of treating or preventing conditions associated with leptin production by administering a pharmaceutically effective amount of a piperazine compound of formula (I), classified in class 514, subclass 255.01.
- IV. Claims 1 (in part) 2-22, drawn to a method of treating or preventing sequelae associated with cancer by administering a pharmaceutically effective amount of a piperazine compound of formula (I), classified in class 514, subclass 255.01.

- V. Claims 1 (in part) 2-22, drawn to a method of treating or preventing cancer metastasis by administering a pharmaceutically effective amount of a piperazine compound of formula (I), classified in class 514, subclass 255.01.
- VI. Claims 1 (in part) 2-22, drawn to a method of treating or preventing diseases or conditions related to production of cytokines at inflammatory sites by administering a pharmaceutically effective amount of a piperazine compound of formula (I), classified in class 514, subclass 255.01.
- VII. Claims 1 (in part) 2-22, drawn to a method of treating or preventing tissue damage caused by inflammation induced by infectious agents by administering a pharmaceutically effective amount of a piperazine compound of formula (I), classified in class 514, subclass 255.01.

Inventions I-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are directed to distinct disorders or conditions. A method of treating fibrosis is unrelated to a method of treating Alzheimer's disease, condition associated with leptin production, sequelae associated with cancer, cancer metastasis, diseases or conditions related to production of cytokines at inflammatory sites, or tissue damage caused by inflammation induced by infectious agents because the treatment of one need not treat the other, nor would it be obvious that the treatment of one would treat the other. For example, fibrosis is a disease associated with the lung, Alzheimer's

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disease is a neurodegenerative disorder, and cancer can affect any of multiple organ systems in the body, to name a few. The disorders or conditions of each group are unrelated and distinct and the searches in non-patent literature databases would be extensive and will not overlap thus presenting a search burden to be searched together. Thus, by virtue of the different disorders and conditions of Groups I-VII, these unrelated inventions are distinct. To search Inventions I-VII would provide a search burden on the Examiner.

In the event that Applicant elects either of Groups IV or V for further prosecution on the merits, Applicant is required under 35 U.S.C. 121 to further elect a specific type of cancer for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently claims 1-22 are generic.

In the event that Applicant elects any of Groups I-VII for further prosecution on the merits, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of variously substituted piperazine compounds for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently claims 19-20 are generic.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion to Restriction Requirement

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Due to the complex nature of the instant restriction requirement, a written restriction requirement was necessitated. See MPEP § 812.01.


Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Renee Claytor



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER